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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,774	03/24/2004	Juergen Dannenmaier	N0060US02	2773

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GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER

MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
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1723

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/708,774

Applicant(s)

DANNENMAIER ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
4a) Of the above claim(s) 7-9, 13, 17, 18, 25-35, 37 and 40-43 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 10-12, 14-16, 19-24, 36, 38 and 39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claims 1-43 are pending as amended 12/28/06, of which claims 7-9,13,17,18,25-35,37 and 40-43 are withdrawn.

Election/Restrictions

In response to applicant's arguments regarding the restriction requirement:

Claim 43 was withdrawn because it recites the non-elected species "welded".

Requirement of restriction with respect to the disclosed species is proper, even if not expressly claimed. However, at least claim 31 recites 'sealing adjacent edges of shell portions', which would read on to 'adhesive'.

Applicant elected adhesive as the method of joining the shell. Therefore, claims directed to welding have been withdrawn from consideration. Since an office action has already been issued with this election, the election is made final. However, applicant may rejoin the species claims as and when the generic claims become patentable, if the species claims are made to depend from the generic claims or amended to contain the allowable subject matter from the generic claims. This is applicable to the method claims as well.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,4,5,16, and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (US 5,882,516).

Claims 1,4,5: Gross teaches a hollow fiber membrane cartridge (figure 1) having two internal compartments (20 and 22) separated by a common wall (18), each compartment having hollow fibers (42), with inlets and outlets (34,36,38,40 and 44), and one of the longitudinal shell portion forming the smaller of the two compartments has less than half the perimeter. Housing is tubular, and the perimeter is the circumference.

Claim 16 and 19-21: the functional arrangement of the filter in figure 1 and 2 are the smaller side is for ultrafiltration and the larger side is for dialysis – see column 2 lines 33-44. The exterior surface of the hollow fibers of the smaller chamber is in fluid communication with the interior side of the hollow fibers of the larger chamber.

Claim 22-24: the cartridge is assembled as claimed – see figures 1 and 2.

2. Claims 6,10-12 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gross.

Claim 6 recites longitudinal seams in the shell, and claims 10-12 recite the assembly process of the shell. However, these limitations are purely for the process of making the device, which do not other wise make any structural difference to the device. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

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process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross

Claims 2 and 3 recite the perimeter of the shell portions as less than a third or a quarter of the housing, which is not specifically taught by the reference. However, the size of the shell would depend on the size of the filter to be accommodated, which would depend on the quantity of fluid to be processed, and one of ordinary skill in the art could optimize this size for the intended purpose. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re *Boesch and Slaney*, 205 USPQ 215 (CCPA 1980); In re *Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

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4. Claims 14,15,36,38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross as applied to claim 1 above, and further in view of Pope et al (US 2003/0102264).

Claims differ from the teaching of Gross in the recitation of the longitudinal shell portions having material with different refractive index, and particularly, polycarbonate and polypropylene. Applicant's stated purpose for the different refractive index in the materials is for monitoring the weld quality between the two shell portions, which is only a manufacturing step, and does not appear to otherwise contribute to the structure of the product. Since no other criticality appears to be disclosed for the choice of the materials, and because applicant elected 'adhesive' as the means for joining the shell portions, the choice of the refractive index of the material, or the choice of polypropylene and polycarbonate, are not patentable limitations. Pope teaches that both polypropylene and polycarbonate can be used for making the dialyzer shell, with polycarbonate being better for visibility, whereas polypropylene is cheaper (see paragraph 20). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Pope in the teaching of Gross to have either, or a combination, of polypropylene and polycarbonate. One would use polycarbonate over polypropylene for the parts that require transparency, such as the part of the shell where blood flows through the membrane, so that any blood leak is clearly visible, and polypropylene for others to reduce the cost.

Response to Arguments

Applicant's arguments filed 12/28/06 have been fully considered but they are not persuasive.

Regarding the Gross reference, the Examiner agrees that Gross does not expressly state the argued limitation. However, if one looks at the figures of Gross, it is very clear that the smaller shell portion would 'describe' a smaller portion of the perimeter of the housing (which is the circumference of the cylindrical housing). Now, the perimeter of the housing 'described' by the shell portions would be about half of the circumference, if the two portions were of about the same size. Since one is less than the other, the smaller one would have less than half of the circumference of the housing. Since the reference does not specifically limit the sizes of the two modules within the housing, even claims 2 and 3 would be anticipated by the reference. Applicant also does not attribute any significance to this limitation for consideration towards patentability.

Regarding claims 6 and 10-12, the limitations that would make the method of assembly easier is not patentable in the product claim. They may be patentable when recited in the method claims. In re Thorpe is properly applied. In claims 10-12, the cited limitations are for the parts of the product before assembly, what is claimed is an assembled product. The assembled product must be structurally discernable and non-obvious from the prior art to overcome the prior art; not the parts that go into the assembly.

Arguments against the optimization of the size for claims 2 and 3 are not convincing. One could of course have any size shell and fit any size bundle in it, but

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normally one would be inclined to fit a smaller bundle in a smaller shell; there is nothing inventive about it.

With respect to the Pope reference, adhesive and welding: applicant voluntarily elected adhesive, the Examiner did not force it up on the applicant. However, had applicant elected 'welding' as the means for joining, even then the state of the product claims would not have been any different. A structural limitation which is distinguishable from the prior art and which has advantages in manufacturing *may be* patentable; however, the instant claims do not recite such a structural limitation that can be distinguished from that of the prior art, or the combination of prior arts. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

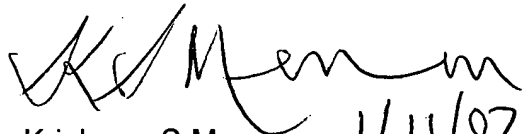
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Krishnan S Menon
Primary Examiner
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1/11/07